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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/662,621	09/15/2003	Michael S. Williams	9362-4	9764
20792	7590	09/25/2006	EXAMINER	
MYERS BIGEL SIBLEY & SAJOVEC			LEVY, NEIL S	
PO BOX 37428			ART UNIT	
RALEIGH, NC 27627			PAPER NUMBER	
			1615	

DATE MAILED: 09/25/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/662,621	Applicant(s) WILLIAMS ET AL.	
	Examiner NEIL LEVY	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 27-49 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 27-49 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

The final rejection is withdrawn, and the following rejections are entered, & reinstated .

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 27-49 are rejected under 35 U.S.C. 112, first paragraph, as based on a disclosure which is not enabling. A description of what is meant by MASKING, critical or essential to the practice of the invention, but not included in the claim(s) is not enabled by the disclosure. See *In re Mayhew*, 527 F.2d 1229, 188 USPQ 356 (CCPA 1976).

Masking is stated to be known but no example or identification of the masking techniques as to how they were used by applicant as applied to the claimed polymeric non-erodible or erodible ,materials, to provide prosthesis, is evident.

The specification (pages 8 and 9) identifies the same polymers as erodible and non-erodible-polyacrylates, polyesters, PET (a polyester, not specifically defined or otherwise identified in the specification, but assumed to be a polyester). There is nothing in the specification that supports the same polymer as erodible & non erodible; in fact, we find no time lines associated with erodible; all materials are erodible , given enough time, & the lack of differentiation between applicant's polymers.

Claims 27- 38,46 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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Absent a clear presentation of MASKING in the specification, it is not possible to determine the meets & bounds of the claimed invention, as the term is open to multiple interpretations.

Claims 27-49 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over BAWA et al 6071439.

BAWA reports use of the instant intraluminal prostheses (column 6, lines 14-28) inclusive of intraocular lenses, surgical devices, heart valves, intrauterine devices, surgical implants, artificial ureters, vessel substitutes (the instant stents), catheters, mouth guards, denture liners, and intraocular devices. Instant claims to portions of the prostheses of erodible polymers of hydrogel, polyacrylate, polyethylene glycol, polycarbonate are met by the monomers of which BAWA's polymers are made (column 3, lines 4, 5, and 14-48). In vivo use is possible after supercritical carbon dioxide (SCF) extraction of alcohol and hydrophobic elements, the instant toxins (column 4, lines 49-67) and shown to be 10 times better than conventional toxin extraction. Example 1, Table 1, shows one in the art can vary the temperature and pressure to optimize toxin removal, and SCF removal (purge). Purging of SCF/toxins would result in toxin removal as the SCF returns to gas state. Operations are in enclosed chambers. Added co-solvents are used in spiking (column 4, lines 11-22), and known to one in SCF technology. Specifying coatings is not evident, but there is recognition of films (column 6, lines 10-17) and one in the art would obviously include prostheses coatings as part of the fabrication process.

Masking is seen as the plasma treatment (Example 3B) followed by SCF with resultant removal of toxins. Note the instant specification provides no identification of what constitutes the masking process; BAWA indicates plasma treatment incorporates oxygen into prostheses, while SCF removes residual solvents.

Claims 27-49 are rejected under 35 U.S.C. 103(a) as being unpatentable over HILE et al '2000 in view of COOK et al 5916585.

Although the PLGA (2.1 of page 178) prostheses of HILE are not stated to be intraluminal, the polymers, drug delivery functionality and SCF treatment are the same as of the instant invention. PLGA (column 9, bottom) is known to be used in intraluminal prostheses, as shown by COOK (column 6, lines 44-50) as a coating of a stent (Example 24).

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Example 19 shows coatings of PGLA. Masking is seen as the PEI coating followed by drug grafting. Solvents and residuals are not addressed. Given HILE, it would have been obvious to one of ordinary skill at the time of the instant invention, producing the Cook implantables, to use SCF to remove solvents and residual materials from prostheses made or coated with PLGA, since HILE shows adjustment of time of extraction (page 183) can remove as much of the solvents as needed to provide suitable in vivo prostheses.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NEIL LEVY whose telephone number is 571-272-0619. The examiner can normally be reached on Tuesday-Friday, 7 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, MICHAEL WOODWARD can be reached on 571-272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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A handwritten signature in black ink, appearing to read "Neil Levy". The signature is fluid and cursive, with a long horizontal stroke at the end.

NEIL LEVY
Primary Examiner
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